DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 18, 2014

MiVi Neuroscience, LLC
Ms. Michelle Straight
VP of Quality & Regulatory
10900 73rd Avenue North, Suite 150
Maple Grove, MN 55369

Re: K140557
Trade/Device Name: MiVi 6F Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 14, 2014
Received: August 15, 2014

Dear Ms. Straight,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140557

Device Name
MiVi 6F Guide Catheter

Indications for Use *(Describe)*
The MiVi 6F Guide Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

10900 73rd Ave. North, Suite 150
Maple Grove, MN 55369

510(k) SUMMARY: K140557

Date Prepared: 3-Mar-2014

Submitter's Name / Contact Person

Manufacturer
MiVi Neuroscience, LLC
10900 73rd Ave N, Suite 150
Maple Grove, MN 55369

Contact Person
Michelle Straight
Vice President of RA/QA
Phone: 612-940-7240
Fax: 763-577-1044
Email: mstraight@mivi.neuro.com

General Information

Trade Name	MiVi 6F Guide Catheter
Common / Usual Name	Guide Catheter
Classification Name **Regulatory Classification**	Percutaneous Catheter (21 CFR 870.1250, Product Code DQY)
Class	II
Panel	Neurodiagnostic and Neurotherapeutic Device (NNDB) Division of Neurological and Physical Medicine Devices (DNPMD)
Predicate Device(s)	Stryker Concentric® Medical, Inc. K110483 Modified HD Guide Catheter Stryker Concentric® Distal Access Catheters Models 90120, 90121, 90130, 90131, 90160, 90161 and 90162

Device Description

The MiVi 6F Guide Catheter consists of a single lumen, braided, variable stiffness shaft designed for use in facilitating the insertion and guidance microcatheters into a selected blood vessel in the peripheral, coronary or neurovascular system. A radiopaque marker is included on the distal end for angiographic visualization. The catheter shaft has a hydrophilic coating to reduce friction during use. A luer hub on the proximal end allows attachments for flushing, insertion of catheters and aspiration. It is used in junction with a rotating hemostatic valve with side-arm adapter for flushing, catheter insertion and aspiration. The MiVi 6F Guide Catheter has a straight distal tip and is available in a 110 cm length and 6F diameter.

Intended Use / Indications
The MiVi 6F Guide Catheter is indicated for: use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter.

Principle of Operation
The device will be utilized to endovascularly insert and guide microcatheters under fluoroscopy so that the microcatheters can deliver contrast agents or other devices during diagnostic and/or therapeutic procedures for patients with arterial disease or damage.

Accessories
There are no accessories to the MiVi 6F Guide Catheters.

Comparison to Predicate Devices:

	Subject Device	**Predicate Device**	**Predicate Device**
Feature	**MiVi 6F Guide Catheter**	**Stryker Concentric® Medical, Inc. K110483 Modified HD Guide Catheter Stryker Concentric REF 90170 and 90171**	**Stryker Concentric® Distal Access Catheters REF 90120, 90121, 90130, 90131, 90160, 90161 and 90162**
Classification	II, DQY	II, DQY	II, DQY
Indications for Use	The MiVi 6F Guide Catheter is indicated for use in facilitating the insertion and guidance of microcatheters into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter.	The Modified HD Guide Catheter is indicated for facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter.	The Distal Access Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter.
Materials, Packaging and Sterilization			
Shaft Materials	PTFE lined PEBAX with stainless steel braid	PTFE lined polymer with stainless steel braid	PTFE lined polymer with stainless steel braid
Proximal End Configuration	Hub with female luer conical fitting	Hub with female luer conical fitting	Hub with female luer conical fitting
Packaging	Catheter attached to an SBS packaging card inside PET/PE/Tyvek pouch, inside SBS box	Catheter attached to SBS packaging card inside carton	Catheter attached to SBS packaging card inside carton
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide

	Subject Device	Predicate Device	Predicate Device
Feature	**MiVi 6F Guide Catheter**	**Stryker Concentric® Medical, Inc. K110483 Modified HD Guide Catheter Stryker Concentric REF 90170 and 90171**	**Stryker Concentric® Distal Access Catheters REF 90120, 90121, 90130, 90131, 90160, 90161 and 90162**
Dimensions			
Effective Length	107.3 cm	105 cm 120 cm	115 cm to 136 cm
Outer Diameter	6F	6.3F	3.9F to 5.2F
Inner Diameter	Distal: .054” Proximal: .064”	.070”	.038” to.057”
Tip Shape	Straight	Straight	Straight

Design verification testing of the MiVi 6F Guide Catheter consisted of:

Performance Test	Result
Push/Track	Met established criteria
Stent Crossing	Met established criteria
Tip Stiffness	Met established criteria
Torque Response	Met established criteria
Kink Resistance	Met established criteria
Tensile	Met established criteria
Luer Leakage	Met established criteria
Coating Adhesion	Met established criteria
Coating Uniformity	Met established criteria
Coating Thickness	Met established criteria
Surface Integrity	Met established criteria
Radiopacity	Met established criteria
System Introduction	Met established criteria
Device Compatibility	Met established criteria

Testing was conducted in accordance with ISO 10555-1:2013, ISO 10555-3:2013, AAMI TIR42:2010, ISO 594-1 and ISO 594-2 standards and FDA guidance: FDA Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters September 8, 2010.

Shelf Life Testing (Product and Packaging) and Distribution Shipping Challenge Conditioning and Testing were performed and the devices met established criteria.

Packaging Verification Testing complies with EN ISO 11607-1 and assessed the ability of finished packages to withstand the effects of anticipated hazards of the distribution environment on essential packaging characteristics and the ability of packaging to protect the device and to maintain sterility (sterile barrier testing).

Biocompatibility testing was conducted in accordance with EN ISO 10993-1. MiVi 6F Guide Catheters have been classified according to EN ISO 10993-1:2009, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing* as follows:

Category: Externally Communicating
Contact type: Circulating blood
Contact Duration: Limited exposure (≤24 hours)

Based on this classification, tests relevant to the device described within this premarket notification were selected and conducted in accordance with EN ISO 10993-1 and its applicable sub-parts.

The MiVi 6F Guide Catheter devices meet ethylene Oxide (EO) and ethylene chlorohydrin (ECH) residuals specified in EN ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.
A sterility assurance level (SAL) of 10^{-6} will be demonstrated.

Testing showed the device, including its packaging, to be biocompatible for its intended use as an externally communicating, circulating blood contacting device as classified under EN ISO 10993-1:2009. The MiVi 6F Guide Catheter successfully passed all of the following biocompatibility tests and was found to be safe and effective and substantially equivalent to the predicate device from a biocompatibility perspective.

Test	**Results**	**Conclusions**
Cytotoxicity - ISO MEM Elution Assay	The test article scored '0' at 24, 48, and 72 hours and is considered non-cytotoxic	Not cytotoxic
Irritation or Intracutaneous Reactivity - ISO Intracutaneous Reactivity Test	Animals in the study showed no abnormal clinical signs, no significant dermal reactions at the injection and control sites at the 24, 48, and 72 hour observation period.	Non-irritating
Hemocompatibility Hemolysis - ASTM Hemolysis Direct Contact and Extract Methods	The test article had a blank corrected hemolytic index of 0.1% above the control in the direct contact test. The test article had a blank corrected hemolytic index of 0.0 % above the control in the extract test.	Non-hemolytic
Hemocompatibility Thrombosis - Four Hour Thromboresistance Evaluation in Dogs	The combined analysis of APTT, platelet counts, device weights, and clinical observations indicated that the animal's clotting abilities were not compromised after implantation of the devices. The test article had similar thromboresistance results to the predicate device so was found to be substantially equivalent to it.	Similar thromboresistance characteristics as control Stryker Concentric Guide Catheter Predicate Device.

Test	Results	Conclusions
Hemocompatibility Complement Activation - Complement Activation C3a and SC5b-9)	The test article concentrations of C3a was 1.0 and the predicate device was 3.2 and SC5b-9 was 0.0 and the predicate device was 1.1 so the test article was not found to be an activator of complements. The test article results were also comparable to the predicate device so was found to be substantially equivalent to it.	Comparable to Stryker Concentric Guide Catheter predicate device for complement activation. Not an activator
Pyrogenicity - Limulus Amebocyte Lysate (LAL) Limit Test	Both test articles contained <0.005 EU/mL and <0.200 EU/device	Non-pyrogenic
Sensitization - ISO Guinea Pig Maximization Test	None of the animals challenged with the test article extracts were observed with a sensitization response greater than '0'.	Non-sensitizing
Systemic Toxicity (Acute) - ISO Acute Systemic Injection Test	No clinical signs consistent with toxicity were observed and body weight changes were within acceptable parameters over the course of the study.	Non-toxic
Ethylene Oxide Residuals - Ethylene Oxide and Ethylene Chlorohydrin	The 6F MiVi Guide Catheter had .094 mg EO/device and .015 mg ECH/device so met both the EO and ECH requirements	Met the ISO 10993-7:2008/ requirements for EO residuals.

Summary of Clinical Performance Data
Not applicable as no clinical data was needed to demonstrate substantial equivalence to the predicate devices.

Conclusion
MiVi Neurosciences has determined its 6F Guide Catheter to be substantially equivalent to the current legally marketed predicate devices because of the following:

1. Intended use and indications for use are the same as for the predicate devices.
2. There is no difference in the fundamental scientific technology or the devices.
3. The risk assessments and successful verification testing including testing to EN ISO 10555-1 and EN ISO 10555-3, raise no new questions of safety and effectiveness.